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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,538	05/02/2005	Kei Kiribayashi	271390US0PCT	1631
22850	7590	04/21/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
HENRY, MICHAEL C				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
04/21/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/533,538

**Applicant(s)**

KIRIBAYASHI ET AL.

**Examiner**

MICHAEL C. HENRY

**Art Unit**

1623

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 11-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-20 is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-17, 21-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 10/31/07.

The amendment filed 10/31/07 affects the application, 10/533,538 as follows:

1. Claims 1-5, 18, 19 have been amended. Claims 6-10 have been canceled. New Claims 21-30 have been added. Upon further consideration it was determined that the indicated allowable subject matter of the prior office action mailed 03/13/07 was not appropriate and is consequently withdrawn.

2. The responsive to applicants' arguments is contained herein below

Claims 1-5 and 11-30 are pending in the application

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites "A peritoneal dialysis method, characterized by employing a dialysate comprising adenosine triphosphate or a salt thereof in an effective amount", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US 5,871,477).

In claim 1, applicant claims a composition comprising adenosine triphosphate or a salt thereof, 1,000 to 4,000 mg/dL glucose, and electrolytes; wherein said composition is suitable for use as a peritoneal dialysate. Claims 2-5 are drawn to said composition which contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure.

Isono et al. disclose a composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines

5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used ((see col. 2, lines 5 to 46, especially lines 34-46).

The difference between applicant's composition and the composition of Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made, in view of Isono et al., to prepare a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes in order to use it as a peritoneal dialysate.

One having ordinary skill in the art would have been motivated in view of Isono et al., to prepare a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes in order to use it as a peritoneal dialysate.

In claim 21, applicant claims a peritoneal dialysis method, comprising: administering into the peritoneal cavity of a subject in need thereof an effective amount of a composition comprising adenosine triphosphate or a salt thereof. Claims 22-30 are drawn to said method wherein said composition used contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure, and wherein the subject has specific conditions.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that

organic acids such as lactic acid and citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity.

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46)

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to administer a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of subject in need thereof.

One having ordinary skill in the art would have been motivated in view of Isono et al., to administer a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of a subject in need thereof. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolality that would be physiologically compatible when administered to said subject.

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 18-20 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a peritoneal dialysis method, characterized by employing a dialysate comprising adenosine triphosphate or a salt thereof in an

effective amount. The very relevant prior art document (Isono et al. (US 5,871,477) to this invention discloses a composition comprising adenosine triphosphate, glucose and electrolytes and but does not disclose nor suggest the use of said composition in a peritoneal dialysis method as claimed in the instant invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

April 12, 2008.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623

